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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,020	03/13/2001	Zurit Levine	2786-0168P	9282
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BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
			EXAMINER STRZELECKA, TERESA E	
			ART UNIT 1637	PAPER NUMBER 10

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,020

Applicant(s)

LEVINE ET AL.

Examiner

Teresa E Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Prior to setting forth the Restriction Requirement, it is pointed out that each Group detailed below reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid or nucleic acid sequences, the Applicants must further elect a single amino acid or a single nucleic acid sequence (See MPEP 803.04).

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 5, 7-12, 13 (in part), 16 (in part), drawn to nucleic acids depicted in SEQ ID NO: 1 to 36, vectors comprising nucleic acids, host cells transfected with these vectors and pharmaceutical compositions comprising nucleic acid sequences or vectors, classified in class 536, subclass 23.1, for example.

If Group I is elected, claims 13 and 16 will be examined to the extent that they read on nucleic acid sequences.

II. Claims 3, 4, 13 (in part), 14, 15, 17, 18, drawn to an amino acid sequence encoded by SEQ ID NO: 1 to 36 or depicted in SEQ ID NO: 37 to 72, and a composition comprising the sequence, classified in class 530, subclass 300, for example.

If Group II is elected, claim 13 will be examined to the extent that it reads on amino acid sequence.

III. Claims 6 and 16 (in part), drawn to an antibody to a polypeptide, classified in class 530, subclass 387.1, for example.

If Group III is elected, claim 16 will be examined to the extent that it reads on an antibody.

- IV. Claims 19-30 and 38-40, drawn to methods for detecting variant nucleic acid sequences in a biological sample by hybridizing the sample to nucleic acid sequences of claim 1 or 2 and detecting hybridization complexes, classified in class 435, subclass 6, for example.
- V. Claim 31, drawn to a method of detecting a variant nucleic acid in a sample by amplification of nucleic acids depicted in SEQ ID NO: 1 to 36, classified in class 435, subclass 91.2, for example.
- VI. Claims 32-37, drawn to detection of amino acid sequences of claim 3 using antibodies or detection of antibodies using amino acid sequences, classified in class 435, subclass 7.1, for example.

The inventions are distinct, each from the other because of the following reasons:

- 3. Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group II, the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of Group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

4. Inventions I and III are separate and distinct, as the claims of Group I are drawn to polynucleotides, while the claims of Group III are drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention III would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

5. Inventions I and (IV, V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group I could be used for an entirely different purpose such as in making the polypeptide of Group II, rather than in the methods of Groups IV and V.

6. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polynucleotide of Group I is not required for the method of Group VI.

7. Inventions II and III are separate and distinct, as the claims of Invention II are drawn to polypeptides, while the claim of Group III is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention III would require searching in areas unrelated to polypeptides, and as such, would require an undue burden on the examiner if not restricted.

8. Inventions II and (IV, V) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have

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different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptide of Group II is not required for the method of Groups IV and V.

9. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used for an entirely different purpose such as in making an affinity chromatography column, rather than in the method of Group VI.

10. Inventions III and (IV, V) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibody of Group III is not required for the method of Groups IV and V.

11. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III could be used for an entirely different purpose such as in making a vaccine, rather than in the method of Group VI.

12. Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant

case the different inventions are directed to methods which have different method steps, starting materials and goals.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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JEFFREY FREDMAN
PRIMARY EXAMINER

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September 29, 2003